DDM
Display Date 6-29-04
Publication Date 6-30-04
Certifier N. Hawkins

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004M-0203]

Medical Devices Regulated by the Center for Biologics Evaluation and Research; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved by the Center for Biologics Evaluation and Research (CBER). This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and FDA's Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please include the appropriate docket number as listed in table 1 of this document when submitting a written request. See the SUPPLEMENTARY INFORMATION section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM-17), Food and Drug

cb0421

2004M-0203

N 1

Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

In the FEDERAL REGISTER of January 30, 1998 (63 FR 4571), FDA published a final rule that revised 21 CFR 814.44(d) and 814.45(d) to discontinue individual publication of PMA approvals and denials in the FEDERAL REGISTER, providing instead to post this information on the Internet at http://www.fda.gov. In addition, the regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during the quarter. FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the FEDERAL REGISTER, and FDA believes that the Internet is accessible to more people than the FEDERAL REGISTER.

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting administrative reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a

PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The following is a list of PMAs approved by CBER for which summaries of safety and effectiveness were placed on the Internet from January 1, 2004, through March 31, 2004. There were no denial actions during the period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

Table 1.--List of Safety and Effectiveness Summaries for Approved PMAs Made Available January 1, 2004, through March 31, 2004

PMA No./Docket No.	Applicant	Trade Name	Approval Date
BP 030025/02004M-0203	Trinity Biotech plc	Trinity Uni-Gold Recombigen HIV, Uni-Gold Recombigen HIV Positive and Negative Controls	December 23, 2003

II. Electronic Access

Persons with access to the Internet may obtain the documents at http://www.fda.gov/cber/products.htm.

Dated: 5/17/04
May 17, 2004

Jesse Goodman,
Director,
Center for Biologics Evaluation and Research.

[FR Doc. 04-????? Filed ??-??-04;845 am]
BILLING CODE 4160-01-S